

Appl. No. 09/774,555  
Atty. Docket No. 7998  
Amdt. Dated 11/13/2003  
Reply to Office Action of 03/05/2003  
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### REMARKS

*Claims 1 to 15 are pending in the case. The Examiner has withdrawn claims 5 to 7 and 16 to 32 from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a non-elected invention, following Applicants' election. The Applicants have amended claim 1, to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Support for the present amendments is found throughout the specification and claims, as originally filed. No new matter has been added and no claims fees are believed to be due. The Applicants believe that the present Amendments, and accompanying Remarks, have placed the present application in condition for allowance. Accordingly, timely and favorable action is respectfully requested.*

#### **Rejection under 35 USC § 102(b) over Johnstone**

The Office Action asserts that claims 1-4, 8-11, 13 and 15 are rejected under 35 USC § 102(b) over WO 98/33497 to Johnstone (hereinafter "Johnstone"). Specifically, the Office Action states that Johnstone teaches a composition for stimulating the growth of hair containing prostaglandins such as 13,14-dihydro-17-phenyl-18,19,20-trinor-PGF<sub>2α</sub>-isopropyl ester. The Office Action further states that Johnstone teaches various carriers such as salines, oil solutions and ointments, as well as the addition of other therapeutic compounds such as minoxidil.

The Applicants wish to direct the Examiner's attention to the "Amendments" section of the instant paper, in which the Applicants have amended claim 1, from which the balance of the above-listed claims ultimately depend, to particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. Support for the present amendments is found throughout the specification and claims, as originally filed. Specifically, the Applicants have amended the second general structure included in claim 1 to indicate that the bond between Carbons five (5) and six (6) in said structure cannot be a double bond. The Applicants submit that designation of Carbons 5 and 6 in said claim is consistent with standard prostaglandin nomenclature, and is clear to a person of ordinary skill in the art. In light of the present amendments, the Applicants urge that the 13,14-dihydro-17-phenyl-18,19,20-trinor-PGF<sub>2α</sub>-isopropyl ester prostaglandin is no longer encompassed by amended claim 1, and thus, the present claims cannot be anticipated by the disclosure of Johnstone. Accordingly, the Applicants respectfully request reconsideration and withdrawal of the rejection to claims 1-4, 8-11, 13 and 15 under 35 USC § 102(b) over Johnstone.

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***Rejection under 35 USC § 102(b) over Vos***

The Office Action states that claims 1-4, 8-10 and 13 under 35 USC § 102(b) are rejected as allegedly being anticipated by WO Patent Number 99/12895 to Vos et al (hereinafter "Vos"). Specifically, the Office Action states that Vos teaches a generic group of prostaglandin F analogs useful as FP agonists, such as 13,14-dihydro-16-(phenylthio)tetranor Prostaglandin F<sub>1α</sub> methyl ester. The Office Action states that Vos further teaches various carriers including talc, polyethylene glycol, water and glycerin, as well as various routes of administration and dosage ranges for said compounds.

The Applicants wish to direct the Examiner's attention to the "Amendments" section of the instant paper, in which the Applicants have amended claim 1, from which the balance of the aforementioned claims ultimately depend, to remove CH<sub>2</sub>NH and CH<sub>2</sub>S from the definition "x" therein. Support for the present amendments is found throughout the specification and claims, as originally filed. In light of the present amendments, the Applicants respectfully submit that the 13,14-dihydro-16-(phenylthio)tetranor Prostaglandin F<sub>1α</sub> methyl ester compound of Vos is no longer encompassed by the present claims, and thus, the present claims cannot be anticipated by the disclosure of Vos. Accordingly, reconsideration and withdrawal of the rejection to claims 1-4, 8-10 and 13 under 35 USC § 102(b) are respectfully requested.

***Rejection under 35 USC § 103(a) over Johnstone***

The Office Action states that claims 1-4 and 8-15 are rejected under 35 USC § 103(a) as purportedly being obvious over Johnstone. Specifically, the Office Action states that Johnstone teaches a composition for stimulating the growth of hair containing prostaglandins such as 13,14-dihydro-17-phenyl-18,19,20-trinor-PGF<sub>2α</sub>-isopropyl ester. The Office Action further states that Johnstone teaches various carriers, such as salines, oil solutions and ointments, as well as other therapeutic compounds such as minoxidil.

The Applicants wish to direct the Examiner's attention to the "Amendments" section of the instant paper, in which the Applicants have amended claim 1, from which the balance of the above-listed claims ultimately depend, to particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. Specifically, the Applicants have amended claim 1 to remove the 13,14-dihydro-17-phenyl-18,19,20-trinor-PGF<sub>2α</sub>-isopropyl ester prostaglandin compound of Johnstone from the scope of the present claims. The Applicants wish to underscore to the Examiner that it would not have been obvious for a person of ordinary skill in

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the art to make any of the species of prostaglandin analogs of the genus taught by Johnstone. Contrary to the assertion included in the Office Action, the species of the genus taught by Johnstone are not all useful (or active) in the context of mammalian hair treatment. Indeed, Johnstone discloses numerous classes of prostaglandin compounds, all of which are purportedly useful in the treatment of glaucoma. However, the Applicants, following extensive research, testing and analysis, have discovered that only a single class of prostaglandin compounds, namely Prostaglandin F compounds, are useful in the treatment of mammalian hair (and hairless) indications. Johnstone provides no guidance that would enable a person of ordinary skill in the art to readily ascertain which of the numerous prostaglandin compounds disclosed, if any, are useful in the treatment of mammalian hair conditions. Indeed, the Applicants, following the aforementioned testing and analysis, have learned that the above-described isopropyl ester prostaglandin compound, for example, does not demonstrate any meaningful activity in the treatment of mammalian hair (and hairless) conditions. Thus, the Applicants submit that it would not have been obvious to a person of ordinary skill in the art to make the species of prostaglandin analogs taught by the genus of Johnstone for use in the treatment of mammalian hair conditions. The Office Action fails to establish a *prima facie* case to the contrary. Accordingly, the Applicants respectfully request reconsideration and withdrawal of the rejection to claims 1-4, 8-15 under 35 USC § 103(a) over Johnstone.

***Rejection under 35 USC § 103(a) over Vos***

The Office Action states that claims 1-4 and 8-15 are rejected under 35 USC § 103(a) as purportedly being obvious over Vos. Specifically, the Office Action states that Vos teaches a generic group of prostaglandin F analogs useful as FP agonists such as 13,14-dihydro-16-(phenylthio)tetranor Prostaglandin F<sub>1 $\alpha$</sub>  methyl ester, as well as various carriers including talc, polyethylene glycol, water and glycerin. The Office Action further states that Vos teaches various routes of administration and dosage ranges for the subject compounds.

The Applicants respectfully direct the Examiner's attention to the "Amendments" section of the instant paper, in which the Applicants have amended claim 1, from which the balance of the aforementioned claims ultimately depend, to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. In light of the present amendments, the Applicants respectfully submit that the 13,14-dihydro-16-(phenylthio)tetranor Prostaglandin F<sub>1 $\alpha$</sub>  methyl ester compound of Vos is no longer encompassed by the present claims, as amended. Moreover, the Applicants submit that there exist several, other material differences between the compounds of Vos and those of the present invention. Namely, the bond connecting the top (alkyl) chain of the

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general structure in claim 1 of the present application is clearly designated as being either alpha ( $\alpha$ ) or beta ( $\beta$ ) whereas *Wos* defines the same bond to be only alpha ( $\alpha$ ). Further, present claim 1 defines the bond connecting the C<sub>11</sub> (alcohol) position of the claimed prostaglandin structure to be alpha ( $\alpha$ ) whereas *Wos* defines the same bond to be alpha ( $\alpha$ ) or beta ( $\beta$ ). Thus, the Applicants respectfully submit, and strongly urge, that it would not have been obvious to a person of ordinary skill in the art at the time the invention was made to make the species of prostaglandin F analogs of the genus taught by *Wos*. The Office Action fails to establish a *prima facie* case to the contrary. Accordingly, reconsideration and withdrawal of the rejection to claims 1-4 and 8-15 under 35 USC § 103(a) are respectfully requested.

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**CONCLUSION**

Applicants have made an earnest effort to place the present claims in condition for allowance. WHEREFORE, entry of the amendments provided herewith, reconsideration of the claims as amended in light of the Remarks provided, withdrawal of the claims rejections, and allowance of claims 1-15, are respectfully requested. In the event that issues remain prior to allowance of the noted claims, then the Examiner is invited to call Applicants' undersigned attorney to discuss any remaining issues.

Respectfully submitted,

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